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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,945	05/06/2005	Pedro Harold Han Hermkens	0-2002.723 US	1701
67706 7590 06/03/2008 ORGANON USA, INC. c/o Schering-Plough Corporation 2000 Galloping Hill Road Mail Stop: K-6-1, 1990 Kenilworth, NJ 07033				
EXAMINER				
MORRIS, PATRICIA L				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/534,945

**Applicant(s)**

HERMKENS ET AL.

**Examiner**

Patricia L. Morris

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) 12, 15 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 14 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/06)  
Paper No(s)/Mail Date 5/6/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-11, 13, 14 and 17-19 are under consideration in this application.

Claims 12, 15 and 20 are held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

#### ***Election/Restrictions***

Applicant's election with traverse of Group III, compound 120 in example 25 and treatment of benign prostrate hyperplasia in the reply filed on February 28, 2008 is acknowledged. The traversal is on the grounds that Groups I to VI do not constitute separate patentably distinct inventions. This is not found persuasive for the reasons set forth in the previous Office action. Further, this application is a national stage application under 35 USC 371 and U.S. practice does not apply herein.

Clearly 37 CFR 1.475 means one when they say a. See the commentary on the rules, 1134 OG 194-209. Note specifically, p. 1134 O.G. 197, col. 2 paragraph numbered (6). PCT Rule 13 provides "claims are permitted to one product, one process of manufacturing the product, and one use of the product". If multiple products, process of manufacture or uses are claimed, the first invention in the category first mentioned in the claims would be considered as the elected invention".

The specification discloses a tremendous list of diseases on pages 6-7 with respect to the possible involvement of an androgen receptor in physio-pathological conditions. However, no nexus of the instant compounds has been inexorably linked to any of the physio-pathological conditions. Nowhere in the specification provides any nexus of the elected core structure with any physio-pathological conditions.

Art Unit: 1625

The lack of unity requirement is deemed sound and proper and is hereby maintained.

This application has been examined to the extent readable on the elected compounds wherein R<sup>1</sup> represents (optionally substituted) pyridyl, R<sup>2</sup> represents substituted phenyl, R<sup>5</sup> – R<sup>9</sup> represent non-heterocyclic groups and X, R<sup>3</sup>, R<sup>4</sup> as set forth in claim 1, exclusively. Claims 18 and 19 have been examined to the extent readable on the elected method of use, *i.e.*, treatment of benign prostrate hyperplasia.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is a lack of description as to how the hydrates are produced and what hydrates are produced in the specification. Vippagunata et al. (Advanced Drug Delivery Reviews 48 (2001) 3-26) recites on page 18 that predicting the formation of hydrates of a compound and the number of molecules of water incorporated into the crystal lattice of a compound is complex and difficult. Guillory (in Brittain et al., NY:Marcel Dekker, 1999, pages 183-226, teach that hydrates can be prepared by recrystallization. Note page

Art Unit: 1625

203 therein. However, not all compounds will form hydrates. Note section 3.4 of Vippagunta et al.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preparing the instant compound and its salts, does not reasonably provide enablement for preparing any and all unknown solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification fails to prepare any hydrates or identify the hydrates obtained.

The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. Applicants are referred to In re Fouché, 169 USPQ 429 CCPA 1971, MPEP 716.02(b).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

***The nature of the invention***

The nature of the invention is the preparation of a compound, its salts and hydrates.

***State of the Prior Art***

Predicting the formation of hydrates of a compound and the number of molecules of water molecules incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of hydrates and hence generalizations cannot be made for a series of compounds. Note section 3.4 of Vippagunta et al.

***The amount of direction or guidance and the presence or absence of working examples***

The working examples in the specification fail to show how any hydrates are produced. Further, Guillory on page 199 recites that compounds originally crystallized as hydrates can lose the water induced by heat or vacuum vaporization.

***The breadth of the claims***

The breadth of the claims is drawn to the preparation of the compound, its salts, and all hydrate forms.

***The quantity of experimentation needed***

The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to the process of preparing all unknown hydrates.

In terms of the 8 Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of unpredictability in the art of the invention, and the poor amount of

Art Unit: 1625

direction provided by applicants. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term hydrate in claim 1 is indefinite to its meaning because it is unclear what is intended by applicants.

Claims 18 and 19 are substantial duplicates.

The claims measure the invention. *United Carbon Co. V. Binney & Smith Co.*, 55 USPQ 381 at 384, col. 1, end of 1st paragraph, Supreme Court of the United States (1942).

The C.C.P.A. in 1978 held “that invention is the subject matter defined by the claims submitted by the applicant. We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim”: *In re Priest*, 199 USPQ 11, at 15.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d

Art Unit: 1625

2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 13, 14 and 17-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 11, 13-18, 23, 31 and 32 of copending Application No. 10/587,192. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant compounds are generically embraced therein having the same use.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1625

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia L. Morris/  
Primary Examiner, Art Unit 1625

plm  
May 29, 2008